

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

LEAH ROYCE HINES,

Plaintiff,

v.

Civil Action No. 2:04-0690

WYETH, d/b/a Wyeth, Inc.;
WYETH PHARMACEUTICALS, INC.;
and PHARMACIA & UPJOHN COMPANY,

Defendants.

CHARGE TO JURY

I. OPENING INSTRUCTIONS

LADIES AND GENTLEMEN OF THE JURY:

Now that you have heard the evidence and the argument,
I want to instruct you as to the law governing this case.

Although you as jurors are the sole judges of the
facts, you are duty bound to follow the law as stated in the
instructions of the Court and to apply the law to the facts as
you find them from the evidence before you.

You are not to single out any one instruction alone as stating the law, but you must consider the instructions as a whole.

Neither are you to be concerned with the wisdom of any rule of law. Regardless of any opinion you may have as to what the law ought to be, it would be a violation of your sworn duty to base a verdict upon any other view of the law than that given in the instructions of the Court.

Evidence in the Case - Stipulations - Charts and Summaries -
Judicial Notice - Inferences Permitted

As I've already informed you, statements and arguments of counsel are not evidence in the case. When, however, the attorneys on both sides stipulate or agree as to the existence of a fact, the jury must, unless otherwise instructed, accept the stipulation and regard that fact as proved.

The Court may take judicial notice of certain facts or events. When the Court declares it will take judicial notice of some fact or event, the jury must, unless otherwise instructed, accept the Court's declaration as evidence, and regard as proved the fact or event which has been judicially noted.

Unless you're otherwise instructed, the evidence in the case always consists of the sworn testimony of the witnesses, regardless of who may have called them; all exhibits received in evidence, regardless of who may have produced them; and all facts

which may have been admitted or stipulated; and all facts and events which may have been judicially noticed.

I would note that the parties have used charts or summaries to help explain the evidence. Those charts or summaries are not evidence. If you find that a chart or summary does not accurately summarize the evidence, you should disregard it.

Any evidence as to which an objection was sustained by the Court, and any evidence ordered stricken by the Court, must be entirely disregarded. I would add that it is counsels' right to make objections to evidence and statements, based upon the applicable rules of evidence. You should not draw any inferences from the fact that counsel raised, or failed to raise, objections, or from the number of objections made by any party, nor should you draw any inferences from the Court's rulings on objections.

Unless you are otherwise instructed, anything you may have seen or heard outside the courtroom is not evidence, and must be entirely disregarded.

You are to consider, then, only the evidence in the case. But in your consideration of the evidence you are not limited to the bald statements of the witnesses. In other words, you are not limited solely to what you see and hear as the witnesses testify. You are permitted to draw, from facts which you find have been proved, such reasonable inferences as seem justified in the light of your experience.

Testimony by Deposition

Much of the testimony before you is in the form of depositions which have been received in evidence. A deposition is simply a procedure where the attorneys for one side may question a witness or an adversary party under oath before a court stenographer prior to trial. This is part of the pretrial process, and each side is entitled to take depositions. You may consider the testimony of a witness given at a deposition according to the same standards you would use to evaluate the testimony of a witness given at trial.

Limiting Instructions

I may have given instructions to you concerning limits placed upon certain evidence. You must consider any evidence admitted for a limited purpose only for that limited purpose.

Credibility of Witnesses - Discrepancies in Testimony

You, as jurors, are the sole judges of the credibility of the witnesses and the weight their testimony deserves. You may be guided by the appearance and conduct of the witness, or by the manner in which the witness testifies, or by the character of the testimony given, or by the evidence to the contrary of the testimony given.

You should carefully scrutinize all the testimony given, the circumstances under which each witness has testified, and every matter in evidence which tends to show whether a witness is worthy of belief. Consider each witness' intelligence, motive and state of mind, and demeanor and manner while on the stand. Consider the witness' ability to observe the matters as to which that witness has testified, and whether that witness impresses you as having an accurate recollection of these matters. Consider also any relation each witness may bear to

either side of the case; the manner in which each witness might be affected by the verdict; and the extent to which, if at all, each witness is either supported or contradicted by other evidence in the case.

Inconsistencies or discrepancies in the testimony of a witness, or between the testimony of different witnesses, may or may not cause the jury to discredit that testimony. Two or more persons witnessing an incident or a transaction may see it or hear it differently; and innocent misrecollection, like failure of recollection, is not an uncommon experience. In weighing the effect of a discrepancy, always consider whether it pertains to a matter of importance or an unimportant detail, and whether the discrepancy results from innocent error or intentional falsehood.

In addition, the testimony of a witness may be discredited or impeached by showing that he or she previously made statements which are inconsistent with his present testimony. As

a general rule, earlier contradictory statements are admissible only to impeach the credibility of the witness, and not to establish the truth of those statements. Where, however, the earlier inconsistent statement was given under oath at a prior hearing or proceeding, the jury may consider that statement as testimony offered for the truth of the matter stated, but only to the extent that statement is, if at all, inconsistent with the witness' present testimony.

If a witness is shown knowingly to have testified falsely concerning any material matter, you have a right to distrust the testimony of that witness in other particulars; and you may reject all the testimony of that witness or give it such credibility as you may think it deserves.

After making your own judgment, you will give the testimony of each witness such weight, if any, as you may think it deserves.

Direct and Circumstantial Evidence

There are, generally speaking, two types of evidence from which a Jury may properly find the truth as to the facts of the case. One is direct evidence -- such as the testimony of an eyewitness. The other is indirect or circumstantial evidence -- the proof of a chain of circumstances pointing to the existence or non-existence of certain facts. As a general rule, the law makes no distinction between direct and circumstantial evidence, but simply requires that the Jury find the facts in accordance with all of the evidence in this case, both direct and circumstantial.

Opinion Evidence - Expert Witness

The rules of evidence ordinarily do not permit witnesses to testify as to opinions or conclusions. An exception to this rule exists as to those whom we call "expert witnesses." Witnesses who, by education and experience, have become expert in some art, science, profession, or calling, may state their opinions as to relevant and material matter, in which they profess to be expert, and may also state their reasons for the opinion.

You should consider each expert opinion received in evidence in this case, and give it such weight as you may think it deserves. If you should decide that the opinion of an expert witness is not based upon sufficient education and experience, or if you should conclude that the reasons given in support of the opinion are not sound or if you feel that it is outweighed by other evidence, you may disregard the opinion entirely.

Burden of Proof - Preponderance of the Evidence

The burden is on the plaintiff in a civil action, such as this, to prove every essential element of her claims by a preponderance of the evidence. If the proof should fail to establish any essential element of one or more of plaintiff's claim by a preponderance of the evidence in the case, the jury must find for the defendants as to that unproven claim or claims.

To "establish by a preponderance of the evidence" means to prove that something is more likely so than not so. In other words, a preponderance of the evidence in the case means such evidence, when considered and compared with that opposed to it, has more convincing force, and produces in your minds beliefs that what is sought to be proved is more likely true than not true.

In determining whether any fact in issue has been proved by a preponderance of the evidence in the case, the jury

may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

Preponderance of the evidence does not mean the greater number of witnesses but means the weight of evidence. If you find that the evidence on a fact is evenly divided, then plaintiff has not proven that fact by a preponderance of the evidence.

Similarly, the defendants have asserted one affirmative defense, namely, the statute of limitations. I will tell you more about that later in these instructions. For now, I will say that if defendants fail to prove any essential element of that affirmative defense by the preponderance of the evidence, you must find against defendants as to it.

While the burden is on the plaintiff to prove her claim, and defendants to prove their affirmative defense, by a

preponderance of the evidence, this rule does not require proof to an absolute certainty, since proof to an absolute certainty is seldom possible in any case. In a civil case such as this, as opposed to criminal cases, it is proper to find that the burden has been met, if, after consideration of all of the evidence in the case, you believe that what is sought to be proved on that issue is, by the weight of the evidence, even in the slightest degree, more likely true than not true.

Corporations

Defendants are corporations. Corporations are considered persons by the law, and all persons are equal before the law. Corporations, whether large or small, are entitled to the same fair and impartial consideration by you as any other person. A corporation may act only through its agents or employees. In general, an agent or employee of a corporation may bind the corporation by acts done or words said while acting within the scope of authority delegated to him or her by the corporation or while performing his or her duties as an employee.

II. PLAINTIFF'S CLAIMS AND DEFENDANTS' AFFIRMATIVE DEFENSE

Plaintiff may seek to recover for injuries caused by a defective product that is faulty in its design or, alternatively, in its warnings, instructions, or labels. So a product may be defective if it is defectively designed or if it has defective warnings, instructions, or labels. Plaintiff alleges both of these types of claims separately against defendants.

Specifically, plaintiff asserts that defendants defectively designed Premarin, Provera and Prempro, which I will refer to hereafter as the "products," and that the defective design proximately caused her breast cancer. She also asserts that defendants failed to adequately warn her that the products could cause her to develop breast cancer. Finally, plaintiff asserts that defendants breached the implied warranty of merchantability, in that their products were not fit for their ordinary purpose, again because they did not adequately warn of breast cancer risks.

III. ELEMENTS AND DEFINITIONS

Plaintiff has alleged five claims for relief. I will discuss each of them with you now. The first claim is that defendants, or either of them alone, defectively designed the products furnished to plaintiff. In order to prove this claim, plaintiff must demonstrate the following four elements by a preponderance of the evidence:

First: Plaintiff was exposed to one of the defendants' products;

Second: That one or more of the products to which she was exposed were defective in design;

Third: The design defect proximately caused plaintiff's breast cancer; and

Fourth: Plaintiff suffered damages as a result of her exposure to the product or products.

A product is defective when it is not reasonably safe for its intended use. The standard of reasonableness is determined by what a reasonably prudent manufacturer's standards should have been at the time the product was made. In considering the reasonably prudent manufacturer's standards, you

may take account of the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.

You may also consider the risks versus the benefits of the products involved. For example, if you find that the products cause breast cancer, you may then also ultimately find that defendants' products were not reasonably safe or that their risks outweigh the benefits.

The second claim is that defendants, or either one of them, failed to adequately warn plaintiff, and in this case her doctor, of the breast cancer risks associated with using their products. This type of claim covers situations when a product may be safe as designed and manufactured but which then becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner. In order to prove this claim, plaintiff must demonstrate the

following four elements by a preponderance of the evidence:

First: Defendants, or either one of them, failed to adequately warn plaintiff or her doctor of the risk that their products could cause breast cancer;

Second: The lack of adequate warning rendered the product or products not reasonably safe for a foreseeable use;

Third: The failure to warn of those dangers was a proximate cause of plaintiff's breast cancer; and

Fourth: The product or products caused plaintiff damages.

The third claim is for negligent failure to warn.

Negligence is the failure of a person to use due care or to do something that a reasonable and prudent person would do in the same or similar circumstances. Negligence may also be the doing of something that a reasonable and prudent person would not do in the same or similar circumstances. In order to prove this claim, plaintiff must demonstrate the following four elements by a preponderance of the evidence:

First: Defendants had a duty to exercise reasonable prudence in warning users and their doctors of any dangers or risks associated with, and known or reasonably knowable to defendants, resulting from the foreseeable use of their products;

Second: Defendants, or either one of them, breached that duty;

Third: The failure to reasonably warn of the dangers or risks was a proximate cause of plaintiff's breast cancer; and

Fourth: The product or products caused plaintiff's damages.

You need not be concerned with making a finding as to the first element inasmuch as the court has determined as a matter of law that the named duty exists. You must, however, make a determination as to the remaining three elements, including whether defendants, or either one of them, breached the duty I just mentioned.

With respect to the nature of the warnings, they must have been reasonably calculated to reach plaintiff or her doctor. Also, the law does not require a manufacturer to provide a perfect warning or perfect label to its product. The question is not whether the product could possibly have been made better or more safe by virtue of a different warning or label, but whether defendants used reasonable care at the time the product was marketed.

The fourth claim is also for negligence but of a different type. It arises not from a failure to warn, such as the negligence claim I just discussed, but rather from an alleged failure by defendants, or either one of them, to exercise ordinary care in the design of the products used by plaintiff in order to ensure that they were reasonably safe for their intended use. In order to prove this claim, plaintiff must demonstrate the following four elements by a preponderance of the evidence:

First: Defendants had a duty to exercise ordinary care in the design of the products used by plaintiff in order to ensure that they were reasonably safe for their intended use;

Second: Defendants, or either one of them, breached that duty;

Third: The failure to exercise ordinary care in the design of the product or products used by plaintiff, in order to ensure that they were reasonably safe for their intended use, was a proximate cause of plaintiff's breast cancer; and

Fourth: The product or products caused plaintiff's damages.

Again, you need not be concerned with making a finding as to the first element inasmuch as the court has determined as a matter of law that the named duty exists. You must, again,

however, make a determination as to the remaining three elements, including whether defendants, or either one of them, breached the duty I just mentioned.

Plaintiff's fifth and final claim is for an alleged breach of the implied warranty of merchantability by failing to provide an adequate warning. In order to prove this claim, plaintiff must demonstrate the following elements by a preponderance of the evidence:

First: Defendants, or either one of them, sold a product or products that were not reasonably fit for their ordinary purposes because the product or products' warnings were inadequate; and

Second: The lack of an adequate warning was a proximate cause of plaintiff's breast cancer.

I would now like to give you some further general instructions and definitions relating to plaintiff's claims. To begin, compliance by a manufacturer with any federal or state statute or administrative regulation existing at the time a product was manufactured, or with prescribing standards for design, inspection, testing, manufacture, labeling or warning or

with instructions for use of a product, are not conclusive but may be considered by you in determining whether or not there was a product defect.

In this vein, I want to mention one thing specifically. You are aware that prescription drugs are regulated by the Food and Drug Administration, or FDA. Before a prescription drug can be sold in the United States, the drug must be approved by the FDA as safe and effective. The drug's labeling must also be approved by the FDA before the drug can be sold. In approving drugs and their labeling, the FDA takes into consideration the fact that a drug has some risks and balances that fact against the beneficial uses of the drug.

You may, but are not required to, view evidence that defendants complied with FDA regulations -- including standards for testing, labeling, warnings, or instructions for use of their products -- as evidence that defendants' medication or

medications were adequately labeled and that defendants exercised reasonable care. However, FDA approval does not necessarily absolve the manufacturer of liability. Even if you find that defendants met all FDA regulations and requirements, which are minimum standards, such compliance is not a defense if a reasonable and prudent manufacturer would have taken added precautions.

Conversely, you may, but are not required to, view evidence of defendants' failure to comply with FDA regulations as evidence of negligence on their part. Ultimately, you may give evidence regarding compliance or noncompliance with FDA regulations whatever weight you deem appropriate.

Another principle to keep in mind generally in the area of product liability law is that a manufacturer is not relieved of liability simply because it did not sell or give the product to the user. The defect, however, must be one that existed at the time the product left the control of the manufacturer. At

the same time, many products contain inherent risks that simply cannot be eliminated through design. In such cases, the product is not defectively designed by virtue of the inherent risk.

I have mentioned proximate cause as an element of each of plaintiff's five claims for relief. I now want to explain it to you. The proximate cause is a cause which, in a natural and continuous sequence, produces or promotes damage and without which the damage would not have occurred. This does not mean that the law recognizes only one proximate cause of damage. If two or more causes work together to produce or promote damage, then you may find that each of them was a proximate cause.

A "producing" cause is one that, in natural and continuous sequence, causes or initiates injury and without which the injury would not have occurred. A "promoting" cause is one that, in a natural and continuous sequence, aggravates a preexisting condition or disease and without which the full extent of the injury would not have occurred.

You are asked to consider the full extent of any injury sustained by plaintiff, even though the degree of injury is found by you to have been proximately caused by the aggravation of a condition or disease that already existed. You may not find proximate cause to have been established though for any injury which plaintiff would have suffered had she not taken the product or products manufactured by defendants.

In considering proximate cause with respect to manufacturer warnings to consumers, you must find plaintiff would not have taken the product or products at all (or in the same dose and duration) had she known of the risk of any one of them causing breast cancer and that she would not have contracted breast cancer had she not taken the product or products in the manner that she did. Defendants, or either one of them, are liable only if there is evidence that a warning would have made a difference.

In proving proximate cause, then, plaintiff must demonstrate that the presence of a warning would have caused her not to take the product or products. She must show that the warnings she suggests were necessary and would have caused her to act differently or otherwise change her behavior in a manner that would have avoided her ingestion of the products and the injury she alleges has resulted to her. If you find that a warning by defendants, or either one of them, would not have prevented plaintiff's injury, then you should find for defendant or defendants as to any claims alleging a failure to warn.

Before I leave the subject of causation, I would add that plaintiff must prove by a preponderance of the evidence both general and specific causation for her injuries. General causation involves whether a product is capable of causing a particular injury or condition in the general population, while specific causation involves whether a substance caused a

particular individual's injury. General causation is established by demonstrating, often through a review of scientific and medical literature, that exposure to a substance can cause a particular disease.

Finally, I have one more matter to address regarding plaintiff's failure to warn claims. A product manufacturer is entitled to have its due warnings and instructions followed by those who use its products. When those warnings and instructions are disregarded, and injury results, the manufacturer is not liable if the available warnings and instructions were reasonably calculated to alert the injured party to the risks of use that resulted in the injury.

IV. AFFIRMATIVE DEFENSE

In addition to challenging plaintiff's claims and liability theories, defendants have separately pled an

affirmative defense to all of plaintiff's claims. The law recognizes that a potential claim is foreclosed if not brought within a certain period of time after the elements of the claim accrue. This is known as a statute of limitations. Each of the claims asserted by plaintiff is subject to a two-year statute of limitations.

The statute of limitations as to all of plaintiff's claims began to run when the plaintiff knew, or by the exercise of reasonable diligence should have known, that (1) she had developed breast cancer, (2) that defendants manufactured the products she alleges to have been responsible for her injuries, and (3) that the products had a causal relation to her breast cancer. If you find that defendants, or either one of them as to the claims pled against them separately, have proven this affirmative defense by a preponderance of the evidence, then your verdict should be for the particular defendant or defendants so proving the defense.

V. DAMAGES

If you find for plaintiff and further find that defendants have not proven their affirmative defense, you must determine the damages to which she is entitled. Plaintiff has the burden of proving damages by a preponderance of the evidence. Simply because I am instructing you on how to award damages does not mean that I have any opinion on whether or not defendants should be held liable or whether plaintiff should be awarded damages.

Damages means that amount of money that will reasonably and fairly compensate plaintiff for any claims for relief that you have found her to have proven by a preponderance of the evidence. In determining the amount of these damages, you may award an amount that would reasonably compensate plaintiff. Damages may not be based on speculation or sympathy. They must be based on the evidence presented at trial and only that evidence.

You may award damages that you find to have been proven in the following categories:

- (1) any bodily injuries plaintiff sustained and their effect on her health according to their degree and probable duration;
- (2) any physical pain and mental anguish she suffered in the past and any that she may with reasonable certainty be expected to suffer in the future;
- (3) any disfigurement or deformity and any associated humiliation or embarrassment;
- (4) any inconvenience caused in the past and, with reasonable certainty, any that will be caused in the future; and
- (5) any reasonably necessary medical expenses incurred in the past and any that may with reasonable certainty be expected to occur in the future.

Compensation for things like pain and suffering are general items of damages. There is no formula or measure upon which these damages can be based. That is not to say such damages are unimportant, only that there is no set method to determine such damages. The amount of compensation to be awarded for such injuries is left to your sound discretion as to what is fair and just. Again, however, if you award damages you must

focus on the sum that will fully, fairly, and reasonably compensate the plaintiff for the damages sustained as a result of any claim she has successfully proven by a preponderance of the evidence against defendants or either one of them.

Once again, the mere fact that the court has instructed you on the issue of damages does not mean that you are required or encouraged to return a verdict in favor of the plaintiff. The burden is on plaintiff to prove by a preponderance of the evidence that any injury complained of was proximately caused by defendants' actions, separately or together, as shown by the evidence.

I would mention as well two final matters in closing. The presence or absence of insurance or benefits of any type, whether liability insurance, health insurance, or employment-related benefits for plaintiff is not to be considered by you in any way in deciding the issue of liability or, if you find for

plaintiff, in considering the issue of damages. The existence or lack of insurance or benefits shall not enter into your discussions or deliberations in any way in deciding the issues in this case.

Second, if you find that the plaintiff had a condition before taking defendants' products that was aggravated as a result of taking one or more of those products or that the pre-existing condition made the injury she received as a result of taking one or more of the products more severe or more difficult to treat, plaintiff may recover for the aggravation and for the increased severity or difficulty of treatment, but she is not entitled to recover for the pre-existing condition.

VI. CLOSING CONSIDERATIONS

Sympathy

The Court instructs the jury that sympathy should have no influence whatever upon you or in any way control your verdict. The question of liability and any award of damages, if any, is to be determined under the instructions of the Court, from the evidence heard in the courtroom, and sympathy has no place in your consideration.

All parties expect that you will carefully and impartially consider all of the evidence, accept and follow the law as contained in these instructions, and reach a just verdict, regardless of the consequences.

Verdict - Unanimous - Duty to Deliberate

Ladies and gentlemen of the jury, your verdict must represent the considered judgment of each juror. In order to return a verdict, it is necessary that each juror agree to it. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view to reaching an agreement, if you can do so without sacrifice of conscientious conviction. You must each decide the case for yourself, but only after an impartial consideration of the evidence in the case with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views, and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence, solely because of the opinion of your fellow jurors, or for the mere purpose of returning a verdict.

Remember at all times that you are not partisans. You are judges -- judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

Election of Foreperson - General Verdict

Upon retiring to the jury room, you will select one of your number to act as your foreperson. The foreperson will preside over your deliberations, and will speak for you here in Court.

Forms of verdict have been prepared for your convenience.

[Forms of verdict read]

You will take these forms to the jury room and, when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form which sets forth the verdict upon which you unanimously agree; and then return with your verdict to the courtroom.